



DEPARTMENT OF HEALTH & HUMAN SERVICES

93910d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA FEDERAL EXPRESS**

Our Reference: 2925498

March 18, 2003

Mrs. America S. Lucero, President  
Mary's Malasadas, Inc.  
236 Kalihi Street  
Honolulu, HI 96819

**WARNING LETTER**

Dear Mrs. Lucero:

On October 7 and 10, 2002, we inspected your food manufacturing facility located at 236 Kalihi Street, Honolulu, HI 96819. During the inspection, Investigator Melody M. Ragasa-Leong collected samples of your products "Mary's Portuguese Sweet Rolls" and "Mary's Portuguese Sweet Bread."

Our label review and sample analyses found the products to be misbranded under section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) because they contain color additives subject to certification that are not declared in the ingredient statement as required by 21 CFR 101.22(k)(1). Analyses revealed the presence of undeclared Sunset Yellow and Allura Red. These colors must be individually declared by their common or usual names, FD&C Yellow No. 6 and FD&C Red No. 40 (these names may be abbreviated by omitting the term "FD&C" or the term "No.," e.g., Yellow 6 and Red 40).

The violation listed above is not meant to be an all-inclusive list of deficiencies. It is your responsibility to ensure that all of your products are manufactured and labeled in accordance with all applicable laws and regulations enforced by FDA.

We may take further action if you do not correct this violation, including seizure of your products and/or injunction of your operation.

In addition, after reviewing the labels submitted for Mary's Portuguese Sweet Rolls,

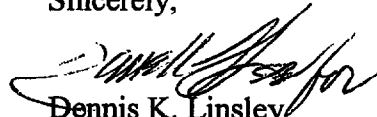
Mary's Portuguese Sweet Bread, and Mary's Banana Walnut Cake, we noted the following:

- The ingredient statements for the sweet rolls and sweet bread do not appear to include all ingredients contained in these products. The flour components reported by the investigator from the inspection are inconsistent with the flour components listed on the labels collected during the inspection. Failure to declare a food's ingredients in accordance with applicable regulations in 21 C.F.R. Part 101 causes the food to be misbranded under section 403(i)(2) of the Act. In addition, the sweet bread label bears the claim "No Preservatives," however, the ingredient statement bears the ingredient "BHA," a known preservative. If the sweet bread contains BHA, the "No Preservatives" claim is false and misleading and the sweet bread is misbranded under section 403(a)(1) of the Act.
- The law requires that the net content be declared in metric units as well as inch-pound units. However, FDA has not published final regulations on how the declaration is to be made. The agency recommends that if you wish to avoid having to change labels again when the regulations on the metric declaration become effective you should add the metric contents statements now, using the guidance provided in the proposed regulations published in the December 21, 1993, Federal Register (58 FR 67444). We expect that any difference between that proposal and the final regulations will be minor and will not by themselves require a label change.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the violation listed above and any actions you are taking in response to our other comments. If you cannot complete all corrections before responding, we expect you will explain the reason for any delay and the time period within which the corrections will be completed.

Your response should be directed to Paul A. Peterson, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any questions regarding any issue in this letter, you may contact Mr. Peterson at (510) 337-6856.

Sincerely,



Dennis K. Linsley  
District Director  
San Francisco District